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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/934,586	08/23/2001	Janice Au-Young	PF-0066-4 DIV	8043
27904	7590 09/26/2003			
INCYTE CORPORATION (formerly known as Incyte Genomics, Inc.) 3160 PORTER DRIVE			EXAMINER	
			CANELLA, KAREN A	
PALO ALTO	O, CA 94304		ART UNIT PAPER NUMBER	
		1642		- 5
			DATE MAILED: 09/26/2003	/

Please find below and/or attached an Office communication concerning this application or proceeding.

	·	Application N .	Applicant(s)				
Office Action Summary		09/934,586	AU-YOUNG				
		Examiner	Art Unit				
		Karen A Canella	1642				
- .	The MAILING DATE f this communication app						
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 mont MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status							
1)[Responsive to communication(s) filed on	<u> </u>					
2a) <u></u>	This action is FINAL . 2b)⊠ Th	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims							
•	4) Claim(s) <u>1-20</u> is/are pending in the application.						
	4a) Of the above claim(s) 12,13 and 17-20 is/are withdrawn from consideration.						
5)[Claim(s) is/are allowed.						
6)[6) Claim(s) <u>1-11 and 14</u> is/are rejected.						
7)[7) Claim(s) is/are objected to.						
•	Claim(s) are subject to restriction and/o	r election requirement.					
• •	tion Papers						
9) The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
 a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 							
Attachment(s)							
2) 🔲 Not	ice of References Cited (PTO-892) ice of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152) hmunt				

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DETAILED ACTION

Acknowledgment is made of applicants election with traverse of Group I, drawn to antibodies which bind to SCAH-2 and methods of making said antibodies. The traversal is on the grounds that the restriction is improper as it separates Groups having the same scope as that of the instant Group I, and therefore it would not be an undue burden on the examiner to examine Groups II and III together with the instant Group because the search for the antibodies and the method claims would substantially overlap. This has been considered but not found persuasive. The methods of Group II and III are drawn to methods having different method objectives and different process steps from the instant methods. As to the question of burden of search, the claims of Groups II and III are classified differently, necessitating different searches in the U.S. Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made FINAL.

Claims 3 and 6 have been amended. Claims 1-20 are pending. Claims 12-13, 17-20, drawn to non-elected inventions, are withdrawn from consideration. Claims 1-11, and 14 are under consideration.

Priority

It is noted that applicant is claiming priority to application 09/225,080 and 08/675,508. Claims 1, 2, 9-11 and 14 are drawn in part to a naturally occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2. It is noted that neither of the parent applications contain support for a naturally occurring amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:2. The prior applications contemplate a "variant" of SCAH" and allelic sequences as alternative forms of SCAH. However, neither of these embodiments provides specific support for the naturally occurring amino acid sequence

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having 90% identity to SEQ ID NO:2. Accordingly, claims drawn to this embodiment will be given priority to the instant filing date.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 9-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "biologically-active fragment". The metes and bound of what constitutes "biologically active" is not defined by the specification. The statement on page 5, lines 24-25 that "biologically active" refers to SCAH having structural, regulatory, or biochemical functions of naturally occurring SCAH", does not set the metes and bounds of the claims without a precise definition of what constitutes the structural, regulatory or biochemical functions of naturally occurring SCAH.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-11 and 14 are drawn to antibodies which specifically bind to an amino acid sequence selected from the group of naturally occurring ammo acid sequences having at least 90% identity to SEQ ID NO:2, biologically active and immunogenic fragments of at least 10

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amino acids of the amino acid residues of SEQ ID NO:2. It is noted that in order to specifically bind SEQ ID NO:2 it is necessary that the antibody not bind to other proteins. thus, in order to make s the claimed antibodies it is necessary to raise antibodies to all possible fragment of SEQ ID NO:2 of at least 10 residues and test said the multitude of antibodies which would result from the experiments against a multitude of other proteins in order to determine if the antibody does indeed specifically bind to SEQ ID NO:2 without cross reactivity to other proteins. Seaver (Genetic Engineering News 1994 Vol 14, No 14: pages 10 and 21) discloses that "selection of the final antibodies requires work with real clinical specimens" to ensure selection of a monoclonal antibody that has high sensitivity and specificity necessary for clinical diagnosis (see fourth column, first full paragraph). Applicant should note that the real sample may contain structurally related substances of the target to be detected. Thus, one of skill in the art would be subject to undue experimentation in order to make the instant antibodies which specifically bind to fragments of SEQ ID NO:2 and naturally occurring proteins amino acid sequences having at least 90% identity to SEQ ID NO:2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-8, are rejected under 35 U.S.C. 102(b) as being anticipated by Blake et al (The Journal of Nephrology, 1993, Vol. 4, pp. 1140-1150). Claim 1 is drawn to an antibody which specifically binds an amino acid sequence of SEQ ID NO:2, a naturally occurring amino acid sequence of SEQ ID NO:2, a biologically active fragment of at least 10 amino acids derived from of SEQ ID NO:2 and an immunogenic fragment of at least 10 amino acids derived from SEQ ID NO:2. Claim 2 embodies the antibody of claim 1 in a pharmaceutical composition. Claim 6 is drawn to a method of making a monoclonal antibody by hybridoma technology. Claim 7 embodies the antibody made by the method of claim 6. Claim 8 embodies the antibody of claim 7 in a pharmaceutical carrier.

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Blake et al disclose an antibody which binds to the Ly-6 antigen. The specification states that the instant SCAH-2 is a member of the LY-6 family g conserved protein sequence important for tertiary structure (page 1, lines 14-17). It is well known in the art that structurally similar proteins can bind antibodies which cross react because the epitope of the antibody is present by virtue of the three dimensional shape of the protein rather than by a linear amino acid sequence (Paul, Immunology (text) 1993, page 243, second column, last full paragraph). It is reasonable to conclude that the antibody described by Blake et al would bind to the instant SCAH-2. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 1-9 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Reiter et al (US 6,267,960). The specific embodiments of claims 1-8 and 14 are set forth above. Claim 9 is drawn in part to a Fab antibody

Reiter et al teach both monoclonal and polyclonal antibodies which bind to PSCA (column 9, lines 1-5), labeled anti-PSCA antibodies (column 9, lines 50-51 and column 12, lines 19-20), methods of making monoclonal antibodies (column 10, lines 55-66) and polyclonal antibodies (column 11, lines 37-62) as well as Fab fragments (column 12, lines 1-4). The attached sequence alignment indicates that PSCA of Reiter et al shares the first 93 amino acids of the instant 123-amino acids of SCAH-2. It would be reasonable to conclude that antibodies which bind to PSCA include antibodies which bind to SCAH-2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blake et al in view of Paul (Fundamental Immunology, 1993, page 460). Claim 3 embodies a method of preparing a polyclonal antibody comprising immunizing an animal with the an immunogenic fragment of SEQ ID NO:2. Claim 4 embodies the antibody produced by the method of claim 3. Claim 5 embodies the antibody of claim 4 in a pharmaceutical carrier

Blake et al disclose monoclonal antibodies which bind to LY-6 and the production of said monoclonals by hybridoma technology. Blake et al do not disclose the production of a polyclonal antibody which binds to LY-6 or the method of producing said polyclonal. Paul et al teach that polyclonal antibody are superior to monoclonal antibodies in situations where a greater degree of crosslinking is desired (page 460, second column, fourth full paragraph). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to make the polyclonal anti-serum to LY-6. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Paul on the superiority of polyclonal antibodies to monoclonal antibodies for purposes such as immunoprecipitations.

Claims 1, 2, 6-8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Blake et al (The Journal of Nephrology, 1993, Vol. 4, pp. 1140-1150). in view of Thorpe and Kerr (Immunochemistry, LabFax, 1994, pages ix-xi and page 127). The specific embodiments

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of claims 1, 2 and 6-8 are recited above. Claim 14 embodies the antibody of claim 1 which is detectably labeled. Blake teaches the specific embodiments of claims 1, 2 and 6-8 for the reasons set forth above. Blake et al teach that indirect labeling was used to visualize the anti-LY-6 antibodies (page 1142, under the heading "Indirect Immunoperoxidase staining"). Blake et al do not teach the anti-LY-6 monoclonal antibodies which are detectably labeled.

Kerr and Thorpe teach methods of directly labeling antibodies as evidenced by the table of contents. Keer and Thrope et al teach immunoassays with enhanced enzyme detection systems which allow for the increase in detection limits (page 127).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to directly label the LY-6 antibody. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Kerr and Thrope on the increase sensitivity that can be obtained through enhanced enzyme detection systems requiring the first antibody to be coupled with an enzyme.

Claims 1, 2, and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Blake et al (The Journal of Nephrology, 1993, Vol. 4, pp. 1140-1150). in view of Schlom ((In: Molecular Foundations of Oncology, 1991, pp. 95-118). The specific embodiments of claims 1, 2 and 6-9 are set forth above. Claims 10 and 11 embody the antibody of claim 1 wherein the antibody is produced by screening a Fab expression library and a recombinant immunoglobulin library, respectively. Blake et al teach the specific embodiments of claims 1, 2 and 6-8 for the reasons set forth above. Blake et al teach that the LY-6 antigen is located in the kidney (page 1142, second column, last full paragraph). Blake et al do not teach a Fab antibody, or screening of antibody libraries.

Schlom teaches that Fab antibodies have advantages over whole antibodies when used in diagnostic assays in vivo because they are less immunogenic than whole antibodies, and clear from the circulation at a faster rate than whole antibodies (page 119, second column, paragraph under the heading "single chain antigen binding proteins). Schlom et al teach the preparation of Fab fragments from recombinant immunoglobulin libraries (pages 123-124, under "Combinatorial Libraries").

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to isolate Fab fragments from a combinatorial immunoglobulin library which specifically bound to the LY-6 antigen..

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Schlom on the improvements associated with the use of Fab fragments in diagnostic assays and the teaching of Blake et al on the presence of the LY-6 antibody in kidneys. One of skill in the art would be motivated to have the Fab fragments which would bind to the LY-6 antigen on kidneys as a means of imaging kidney structure in vivo.

Claims 1-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiter et al (US 6,267,960) in view of Schlom ((In: Molecular Foundations of Oncology, 1991, pp. 95-118). The specific embodiments of the claims and the teachings of Reiter et al over the embodiments of said claims are set forth above. Reiter et al teach that use of Fab fragments is preferable in a therapeutic context as these fragments are generally less immunogenic than whole immunoglobulins. Reiter et all teach that anti-PSCA antibodies may be used systemically to treat cancer (column 12, lines 37-38). Reiter et al do not teach an antibody produced by screening a Fab expression library, or a recombinant immunoglobulin expression library.

Schlom teaches that Fab antibodies have advantages over whole antibodies when used in diagnostic assays in vivo because they are less immunogenic than whole antibodies, and clear from the circulation at a faster rate than whole antibodies (page 119, second column, paragraph under the heading "single chain antigen binding proteins). Schlom et al teach the preparation of Fab fragments from recombinant immunoglobulin libraries (pages 123-124, under "Combinatorial Libraries").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to isolate Fab fragments from a combinatorial immunoglobulin library which specifically bind to the PSCA antigen..

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One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Schlom on the improvements associated with the use of Fab fragments in diagnostic assays and the teachings of Reiter et al on the treatment of cancer by the administration of anti-PSCA antibodies and on the desirability of Fab fragments versus whole antibodies due to the decreased immunogenicity associated with Fab fragments.

.All claims are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D. Patent Examiner, Group 1642 9/23/03.

Marin a. Gamelle

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1 Similarity 100.0%; Pred. No. 7.6e-82;
93; Conservative 0; Mismatches 0; Indels
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TITLE OF INVENTION: PSCA: PROSTATE STEM CELL ANTIGEN
FILE REFERENCE: 30415.54USU1
CURRENT APPLICATION NUMBER: US/09/038,261A
CURRENT FILING DATE: 1998-03-10
PRIOR APPLICATION NUMBER: 08/814,279
PRIOR FILING DATE: 1997-03-10
PRIOR APPLICATION NUMBER: 60/071,141
PRIOR FILING DATE: 1998-01-12
PRIOR FILING DATE: 1998-01-12
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FILE REFERENCE: 30435.54USU1
CURRENT APPLICATION NUMBER: US/09/038,261A
CURRENT FILING DATE: 1998-03-10
FRIOR APPLICATION NUMBER: 08/814,279
PRIOR FILING DATE: 1997-03-10
PRIOR FILING DATE: 1997-01,141
PRIOR FILING DATE: 1998-01-12
PRIOR FILING DATE: 1998-01-13
NUMBER OF SEQ ID NOS: 15
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Best Local Similarity 100.0%; Pred. No. 7.6
Matches 93; Conservative 0; Mismatches
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Parent No. 6541212

Squence 2, Application US/09564129A

Parent No. 6541212

Squence 2, Application US/09564129A

Parent No. 6541212

Parent No. 6541212

Parent No. 6541212

APPLICANT: Raiter, Ovenn V.

APPLICANT: Raiter, Ovenn V.

APPLICANT: Saffran Duglas C.

ITILE DO INVENTION: PSCA: PROSTATE STEW CELL ANTIGEN AND USES THEREOF CURRENT FILING DATE: 2000-05-03

PRIOR APPLICATION UNDERS: 09/139-130

PRIOR PILING DATE: 1995-00-12

PRIOR PILING DATE: 1995-00-12

PRIOR PILING DATE: 1998-00-12

PRIOR PILING DATE: 1998-00-13

PRIOR PILING DATE: 1998-00-13
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US-09-564-329A-6

Sequence 6, Application US/09564329A
Patent No. 6541212
GENERAL INFORMATION:
APPLICANT: Reiter, Robert E.
APPLICANT: Wite, Owen N:
APPLICANT: Saffran, Douglas C.
TITLE OF INVENTION: PSCA: PROSTATE STEM CELL ANTIGEN AND USES THEREOF
FILE REPERENCE: 30435.54US14
CURRENT APPLICATION NUMBER: US/09/564,329A